

Claims:

1. A process for producing a pharmaceutical composition, which comprises:
 - (a) providing a plurality of containers;
 - (b) providing a plurality of excipient solutions;
 - 5 (c) providing a plurality of compound solutions, each having dissolved therein a pharmaceutical compound;
 - (d) dispensing into each container at least one of the excipient solutions with one of the compound solutions so as to form an intimate mixture, a property of each mixture being varied in different containers;
 - 10 (e) incubating the mixture;
 - (f) determining onset of solid-state nucleation;
 - (g) selecting a pharmaceutical compound/excipient combination whereby onset of solid-state nucleation is retarded; and
 - (h) producing a pharmaceutical composition comprising the pharmaceutical compound/excipient combination.
- 15 2. A process according to claim 1, wherein:
 - (a) the property varied in step (d) comprises identity or amount of the excipient or the pharmaceutical compound;
 - 20 (b) each solution comprises an aqueous solution;
 - (c) the mixture simulates gastric juices or intestinal fluids;
 - (d) the compound solution is supersaturated;
 - (e) the plurality of containers are presented in a multiple well plate format;
 - 25 (f) at least the step of dispensing is performed with automated liquid handling apparatus;
 - (g) the intimate mixture is formed using a mixer;
 - (h) the step of incubating the mixture is performed at constant temperature;
 - 30 (i) the temperature is approximately 37 degrees C;
 - (j) the onset of solid-state nucleation is determined by measuring the light scattering of the mixture;

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- (k) the light scattering is measured using a nephelometer;
- (l) the process further comprises a step of determining the crystallinity of the product of solid-state nucleation before selecting the pharmaceutical compound/excipient combination;
- 5 (m) the crystallinity is determined by birefringence screening; or
- (n) a pharmaceutical composition is obtained.

3. A process for producing a pharmaceutical composition, which comprises:

- (a) providing a plurality of containers;
- 10 (b) providing a plurality of excipient solutions;
- (c) providing a plurality of compound solutions, each having dissolved therein a pharmaceutical compound;
- (d) dispensing into each container one of the excipient solutions with one of the compound solutions so as to form an intimate mixture, the excipient being varied in different containers;
- 15 (e) incubating the mixture;
- (f) determining onset of solid-state nucleation;
- (g) selecting an excipient which is found to retard onset of solid-state nucleation; and
- (h) producing a pharmaceutical composition comprising the pharmaceutical compound and the selected excipient.

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4. A pharmaceutical composition obtained by a process according to claim 3.

25 5. A method for assessing excipient-mediated retardation of solid-state nucleation of a pharmaceutical compound, which method comprises:

- (a) providing a plurality of containers;
- (b) providing a plurality of excipient solutions;
- (c) providing a plurality of compound solutions, each having dissolved therein a pharmaceutical compound;

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- (d) dispensing into each container one of the excipient solutions with one of the compound solutions so as to form an intimate mixture, a property of each mixture being varied in different containers;
- (e) incubating the mixture;
- 5 (f) determining onset of solid-state nucleation; and
- (g) ranking the property of the mixture according to time of onset of solid-state nucleation.

6. A method for screening excipients that retard solid-state nucleation of a

10 pharmaceutical compound, which method comprises:

- (a) providing a plurality of containers;
- (b) providing a plurality of excipient solutions;
- (c) providing a plurality of compound solutions, each having dissolved therein a pharmaceutical compound;
- 15 (d) dispensing into each container one of the excipient solutions with one of the compound solutions so as to form an intimate mixture, the excipient being varied in different containers;
- (e) incubating the mixture;
- (f) determining onset of solid-state nucleation; and
- 20 (g) ranking the excipient according to time of onset of solid-state nucleation.

7. A pharmaceutical composition comprising:

- (a) a salt or a liquid form of an API having low solubility in gastric fluid conditions;
- 25 (b) a precipitation retardant; and
- (c) an optional enhancer;

wherein the composition retards crystallization/precipitation of the drug for at least 5 minutes in gastric fluid conditions.

30 8. The pharmaceutical composition according to claim 7, wherein:

- (a) the precipitation retardant is a surfactant;

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- (b) the surfactant has an interfacial tension of less than 10 dyne/cm or a surface tension of less than 42 dyne/cm;
- (c) the surfactant comprises an ether functional group;
- (d) the surfactant is a poloxamer;
- 5 (e) the poloxamer has an interfacial tension of less than 10 dyne/cm or surface tension less than 42 dyne/cm;
- (f) the surfactant is present at a concentration equal to or above the critical micelle concentration;
- (g) the composition comprises an enhancer;
- 10 (h) the composition comprises a cellulose ester as an enhancer;
- (i) the composition comprises HPC or HPMC as an enhancer;
- (j) the composition comprises HPC as an enhancer;
- (k) crystallization/precipitation is retarded for at least 10 minutes;
- (l) crystallization/precipitation is retarded for at least 15 minutes;
- 15 (m) crystallization/precipitation is retarded for at least 20 minutes;
- (n) crystallization/precipitation is retarded for at least 25 minutes;
- (o) crystallization/precipitation is retarded for at least 30 minutes;
- (p) crystallization/precipitation is retarded for at least 35 minutes;
- (q) crystallization/precipitation is retarded for at least 40 minutes;
- 20 (r) crystallization/precipitation is retarded for at least 45 minutes;
- (s) crystallization/precipitation is retarded for at least 60 minutes;
- (t) the API is a sulfonamide API;
- (u) the sulfonamide API is a benzene sulfonamide;
- (v) the benzene sulfonamide is celecoxib, deracoxib, valdecoxib, rofecoxib or eturicoxib;
- 25 (w) the benzene sulfonamide is in the form of an alkali metal or alkaline earth metal salt;
- (x) the aqueous solubility of the API is not more than 0.1 mg/mL when measured at 37 degrees C;
- (y) the aqueous solubility of the API is not more than 10 mg/mL when measured at 37 degrees C;
- 30 (z) the salt is an alkali metal or alkaline earth metal salt;

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- (aa) the metal is sodium, potassium, lithium, or calcium; or
- (bb) the salt is crystalline.

5 9. A process for producing a pharmaceutical composition for delivering a supersaturated concentration of a drug having low aqueous solubility, which process comprises intimately mixing together components:

- (a) a salt or a liquid form of an API having low solubility in gastric fluid conditions;
- 10 (b) a precipitation retardant; and
- (c) an optional enhancer.

10. The process for producing a pharmaceutical composition according to claim 9, wherein:

- 15 (a) the API comprises a sulfonamide API;
- (b) the sulfonamide API is a benzene sulfonamide;
- (c) the benzene sulfonamide is celecoxib, deracoxib, valdecoxib, rofecoxib or eturicoxib;
- (d) the benzene sulfonamide is in the form of an alkali metal or alkaline earth metal salt;
- 20 (e) the aqueous solubility of the API is not more than 0.1 mg/mL when measured at 37 degrees C; or
- (f) the aqueous solubility of the API is not more than 10 mg/mL when measured at 37 degrees C.

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11. The pharmaceutical composition according to claim 7, wherein:

- (a) the bioavailability of the composition orally administered is at least 70%;
- (b) the bioavailability of the composition orally administered is at least 80%;
- (c) the bioavailability of the composition orally administered is at least 85%;
- 30 (d) the bioavailability of the composition orally administered is at least 90%;
- (e) the bioavailability of the composition orally administered is at least 95%;

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- (f) the C_{max} is at least 2 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- (g) the C_{max} is at least 3 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- 5 (h) the C_{max} is at least 4 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- (i) the C_{max} is at least 5 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- 10 (j) the C_{max} is at least 10 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- (k) the C_{max} is at least 25 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- (l) the C_{max} is at least 50 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- 15 (m) the C_{max} is at least 100 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- (n) the C_{max} is at least 250 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- (o) the C_{max} is at least 500 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- 20 (p) the C_{max} is at least 750 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- (q) the C_{max} is at least 1000 fold greater than a neutral form in vivo or in an in vitro dissolution assay;
- 25 (r) the bioavailability of the composition is at least 50% greater than a neutral form;
- (s) the bioavailability of the composition is at least 75% greater than a neutral form;
- (t) the bioavailability of the composition is at least 2 fold that of a neutral form;
- 30 (u) the bioavailability of the composition is at least 3 fold that of a neutral form;
- (v) the bioavailability of the composition is at least 4 fold that of a neutral form;
- (w) the bioavailability of the composition is at least 5 fold that of a neutral form;

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- (x) the bioavailability of the composition is at least 10 fold that of a neutral form;
or
- (y) a linear dose response is generated upon administration from a dose of up to 7 mg/kg.

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12. A pharmaceutical composition comprising a salt or liquid form of a sulfonamide API having low solubility in gastric fluid conditions.

13. The pharmaceutical composition of claim 12, wherein:

- 10 (a) the sulfonamide is a benzene sulfonamide;
- (b) the benzene sulfonamide is celecoxib, deracoxib, valdecoxib, rofecoxib, or eturicoxib;
- (c) the benzene sulfonamide is celecoxib;
- (d) the pharmaceutically acceptable salt is an alkali metal or an alkaline earth metal salt;
- 15 (e) the alkali metal or alkaline earth metal salt is sodium, lithium, potassium, or calcium;
- (f) the salt is crystalline; or
- (g) the salt is amorphous.

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14. A pharmaceutical composition comprising a sodium salt of celecoxib.

15. The pharmaceutical composition of claim 14, wherein the salt form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- 25 (a) said form is a celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 3.57, 8.91, and 10.69 degrees;
- (b) said form is a celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 11.29, 16.69, and 17.13 degrees;
- 30 (c) said form is a celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 9.49, 18.29, and 19.85 degrees;

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- (d) said form is a celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 3.57, 10.69, and 19.85 degrees;
- (e) said form is a celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 13.69, 19.85, and 21.53 degrees;
- 5 (f) said form is a celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 11.29, 22.39, and 23.35 degrees;
- (g) said form is a celecoxib sodium salt and said X-ray diffraction pattern comprises a peak at 19.85 degrees;
- (h) said form is a celecoxib sodium salt and said X-ray diffraction pattern
- 10 comprises peaks at 8.91 and 10.69 degrees; or
- (i) said form is a celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 3.57, 10.69, 13.69, and 19.85 degrees.

16. A pharmaceutical composition comprising a potassium salt of celecoxib.

15 17. The pharmaceutical composition of claim 16, wherein the salt form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (a) said form is a celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 9.11, 12.23, and 19.79 degrees;
- 20 (b) said form is a celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 9.11, 20.97, and 22.81 degrees;
- (c) said form is a celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 12.23, 19.79, and 24.71 degrees;
- 25 (d) said form is a celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 8.13, 12.23, and 19.79 degrees;
- (e) said form is a celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 4.99, 9.11, and 24.71 degrees;
- (f) said form is a celecoxib potassium salt and said X-ray diffraction pattern
- 30 comprises a peak at 19.79 degrees;
- (g) said form is a celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 12.23 and 15.35 degrees; or

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(h) said form is a celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 4.03, 10.61, 15.35, and 22.81 degrees.

18. A pharmaceutical composition comprising a lithium salt of celecoxib.

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19. The pharmaceutical composition of claim 18, wherein the salt form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

(a) said form is a celecoxib lithium salt and said X-ray diffraction pattern comprises peaks at 4.14, 9.04, and 10.71 degrees;

10 (b) said form is a celecoxib lithium salt and said X-ray diffraction pattern comprises peaks at 18.71, 20.52, and 23.00 degrees;

(c) said form is a celecoxib lithium salt and said X-ray diffraction pattern comprises peaks at 10.71, 18.71, and 21.55 degrees;

15 (d) said form is a celecoxib lithium salt and said X-ray diffraction pattern comprises peaks at 9.04, 10.71, and 12.47 degrees;

(e) said form is a celecoxib lithium salt and said X-ray diffraction pattern comprises peaks at 12.47, 15.75, and 20.52 degrees;

(f) said form is a celecoxib lithium salt and said X-ray diffraction pattern comprises a peak at 10.71 degrees;

20 (g) said form is a celecoxib lithium salt and said X-ray diffraction pattern comprises peaks at 9.04 and 15.08 degrees; or

(h) said form is a celecoxib lithium salt and said X-ray diffraction pattern comprises peaks at 12.46, 15.75, 20.52, and 21.55 degrees.

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20. A pharmaceutical composition comprising a calcium salt of celecoxib.

21. The pharmaceutical composition of claim 20, wherein the salt form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

(a) said form is a celecoxib calcium salt and said X-ray diffraction pattern comprises peaks at 7.82, 9.27, and 20.56 degrees;

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- (b) said form is a celecoxib calcium salt and said X-ray diffraction pattern comprises peaks at 3.91, 9.27, and 27.35 degrees;
- (c) said form is a celecoxib calcium salt and said X-ray diffraction pattern comprises peaks at 11.66, 14.93, and 23.08 degrees;
- 5 (d) said form is a celecoxib calcium salt and said X-ray diffraction pattern comprises peaks at 9.27, 20.56, and 27.35 degrees;
- (e) said form is a celecoxib calcium salt and said X-ray diffraction pattern comprises peaks at 16.96, 19.03, and 23.08 degrees;
- (f) said form is a celecoxib calcium salt and said X-ray diffraction pattern comprises a peak at 9.27 degrees; or
- 10 (g) said form is a celecoxib calcium salt and said X-ray diffraction pattern comprises peaks at 3.91 and 20.56 degrees.

22. The pharmaceutical composition of claim 12, wherein the API is celecoxib and
15 wherein the salt further comprises water or a solvent molecule.

23. The pharmaceutical composition of claim 22, wherein the solvent molecule is propylene glycol.

20 24. A pharmaceutical composition comprising celecoxib sodium salt propylene glycol solvate.

25. The pharmaceutical composition of claim 24, wherein the solvate form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (a) said form is a celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 3.77, 7.57, and 11.33 degrees;
- (b) said form is a celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 11.33, 18.69, and 20.65 degrees;
- 30 (c) said form is a celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 16.13, 22.69, and 24.77 degrees;

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- (d) said form is a celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 8.21, 18.69, and 22.69 degrees;
- (e) said form is a celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 14.23, 20.65, and 24.77 degrees;
- 5 (f) said form is a celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises a peak at 3.77 degrees;
- (g) said form is a celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 7.57 and 20.65 degrees; or
- 10 (h) said form is a celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 11.33, 16.13, 18.69, and 22.69 degrees.

26. The pharmaceutical composition of claim 24, wherein the celecoxib sodium salt propylene glycol solvate is a hydrate.

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27. The pharmaceutical composition of claim 26, wherein the hydrate form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (a) said form is a hydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 18.43, 19.21, and 22.13 degrees;
- 20 (b) said form is a hydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 6.97, 13.93, and 19.45 degrees;
- (c) said form is a hydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 3.47 and 21.27 degrees;
- 25 (d) said form is a hydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises a peak at 3.82 degrees;
- (e) said form is a hydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 8.69, 18.45, and 20.84 degrees; or

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(f) said form is a hydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 6.97 and 19.45 degrees.

28. The pharmaceutical composition of claim 24, wherein the celecoxib sodium salt
5 propylene glycol solvate is anhydrous or a dihydrate.

29. A pharmaceutical composition comprising celecoxib potassium salt propylene glycol solvate.

10 30. The pharmaceutical composition of claim 29, wherein the solvate form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (a) said form is a celecoxib potassium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 3.75, 7.47, and 18.31 degrees;
- (b) said form is a celecoxib potassium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 11.33, 18.31, and 21.73 degrees;
- (c) said form is a celecoxib potassium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 15.65, 20.49, and 22.51 degrees;
- (d) said form is a celecoxib potassium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 14.89, 18.31, and 24.97 degrees;
- (e) said form is a celecoxib potassium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 15.65, 20.49, and 23.03 degrees;
- (f) said form is a celecoxib potassium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 7.47, 15.65, and 22.51 degrees;
- (g) said form is a celecoxib potassium salt propylene glycol solvate and said X-ray diffraction pattern comprises a peak at 3.75 degrees;

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5 (h) said form is a celecoxib potassium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 7.47 and 18.31 degrees; or
(i) said form is a celecoxib potassium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 11.33, 15.65, 21.73, and 24.97 degrees.

31. The pharmaceutical composition of claim 29, wherein the celecoxib potassium salt propylene glycol solvate is anhydrous.

10 32. A pharmaceutical composition comprising celecoxib lithium salt propylene glycol solvate.

15 33. The pharmaceutical composition of claim 32, wherein the solvate form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

20 (a) said form is a celecoxib lithium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 3.79, 11.41, and 15.93 degrees;
(b) said form is a celecoxib lithium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 18.29, 19.87, and 20.63 degrees;
(c) said form is a celecoxib lithium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 9.83, 20.63, and 25.09 degrees;
(d) said form is a celecoxib lithium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 8.19, 16.45, and 19.87 degrees;
(e) said form is a celecoxib lithium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 19.19, 21.13, and 25.09 degrees;
(f) said form is a celecoxib lithium salt propylene glycol solvate and said X-ray diffraction pattern comprises a peak at 11.41 degrees;
(g) said form is a celecoxib lithium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 18.29 and 20.63 degrees; or
30 (h) said form is a celecoxib lithium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 3.79, 8.19, 15.93, and 25.09 degrees.

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34. A pharmaceutical composition comprising a trihydrate of celecoxib sodium salt propylene glycol solvate.

35. The pharmaceutical composition of claim 34, wherein the trihydrate form is
5 characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (a) said form is a trihydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 6.95, 13.95, and 25.71 degrees;
- 10 (b) said form is a trihydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 3.43, 6.95, and 19.43 degrees;
- (c) said form is a trihydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 11.83, 16.39, and 21.21 degrees;
- 15 (d) said form is a trihydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 10.25, 18.21, and 22.61 degrees;
- (e) said form is a trihydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 12.95, 16.39, and 22.61 degrees;
- 20 (f) said form is a trihydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises a peak at 16.39 degrees;
- (g) said form is a trihydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 6.95 and 21.21 degrees; or
- 25 (h) said form is a trihydrate of celecoxib sodium salt propylene glycol solvate and said X-ray diffraction pattern comprises peaks at 3.43, 10.25, 13.95, and 25.71 degrees.

36. A pharmaceutical composition comprising celecoxib sodium salt isopropanol
30 solvate.

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37. The pharmaceutical composition of claim 36, wherein the solvate form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (a) said form is a celecoxib sodium salt isopropanol solvate and said X-ray diffraction pattern comprises peaks at 3.43, 7.03, and 10.13 degrees;
- 5 (b) said form is a celecoxib sodium salt isopropanol solvate and said X-ray diffraction pattern comprises peaks at 11.75, 14.11, and 16.61 degrees;
- (c) said form is a celecoxib sodium salt isopropanol solvate and said X-ray diffraction pattern comprises peaks at 17.61, 18.49, and 22.81 degrees;
- 10 (d) said form is a celecoxib sodium salt isopropanol solvate and said X-ray diffraction pattern comprises peaks at 10.13, 20.97, and 22.81 degrees;
- (e) said form is a celecoxib sodium salt isopropanol solvate and said X-ray diffraction pattern comprises peaks at 17.61, 22.81, and 25.93 degrees;
- 15 (f) said form is a celecoxib sodium salt isopropanol solvate and said X-ray diffraction pattern comprises peaks at 7.03, 16.61, and 18.49 degrees;
- (g) said form is a celecoxib sodium salt isopropanol solvate and said X-ray diffraction pattern comprises a peak at 16.61 degrees;
- (h) said form is a celecoxib sodium salt isopropanol solvate and said X-ray diffraction pattern comprises peaks at 11.75 and 20.97 degrees; or
- 20 (i) said form is a celecoxib sodium salt isopropanol solvate and said X-ray diffraction pattern comprises peaks at 7.03, 14.11, 17.61, and 22.81 degrees.

38. A pharmaceutical composition comprising a co-crystal, which comprises celecoxib and nicotinamide.

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39. The pharmaceutical composition of claim 38, wherein the co-crystal is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (a) said form is a co-crystal comprising celecoxib and nicotinamide and said X-ray diffraction pattern comprises peaks at 9.62, 17.78, and 20.44 degrees;
- 30 (b) said form is a co-crystal comprising celecoxib and nicotinamide and said X-ray diffraction pattern comprises peaks at 9.63, 22.10, and 24.70 degrees;

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- (c) said form is a co-crystal comprising celecoxib and nicotinamide and said X-ray diffraction pattern comprises peaks at 16.01, 19.31, and 21.19 degrees;
- (d) said form is a co-crystal comprising celecoxib and nicotinamide and said X-ray diffraction pattern comprises peaks at 17.78, 20.44, and 23.80 degrees;
- 5 (e) said form is a co-crystal comprising celecoxib and nicotinamide and said X-ray diffraction pattern comprises peaks at 9.63, 16.01, and 19.31 degrees;
- (f) said form is a co-crystal comprising celecoxib and nicotinamide and said X-ray diffraction pattern comprises a peak at 17.78 degrees;
- (g) said form is a co-crystal comprising celecoxib and nicotinamide and said X-ray 10 diffraction pattern comprises peaks at 3.77 and 9.63 degrees; or
- (h) said form is a co-crystal comprising celecoxib and nicotinamide and said X-ray diffraction pattern comprises peaks at 7.56, 17.78, 19.31, and 22.10 degrees.

40. A pharmaceutical composition comprising a hydrate of celecoxib potassium salt.

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41. The pharmaceutical composition of claim 40, wherein the hydrate form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (a) said form is a hydrate of celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 3.69, 8.99, and 13.35 degrees;
- 20 (b) said form is a hydrate of celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 10.65, 13.35, and 20.05 degrees;
- (c) said form is a hydrate of celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 18.85, 21.45, and 22.39 degrees;
- (d) said form is a hydrate of celecoxib potassium salt and said X-ray diffraction 25 pattern comprises peaks at 3.69, 13.35, and 24.77 degrees;
- (e) said form is a hydrate of celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 10.65, 18.85, and 26.71 degrees;
- (f) said form is a hydrate of celecoxib potassium salt and said X-ray diffraction 30 pattern comprises a peak at 20.05 degrees;
- (g) said form is a hydrate of celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 3.69 and 13.35 degrees; or

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(h) said form is a hydrate of celecoxib potassium salt and said X-ray diffraction pattern comprises peaks at 8.99, 18.85, 20.05, and 22.39 degrees.

42. A pharmaceutical composition comprising a hydrate of celecoxib sodium salt.

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43. The pharmaceutical composition of claim 42, wherein the hydrate form is characterized by a powder X-ray diffraction pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (a) said form is a hydrate of celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 3.51, 11.59, and 20.17 degrees;
- (b) said form is a hydrate of celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 20.17 and 11.59 degrees;
- (c) said form is a hydrate of celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 19.57, 21.55, and 31.67 degrees;
- (d) said form is a hydrate of celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 3.51 and 8.89 degrees;
- (e) said form is a hydrate of celecoxib sodium salt and said X-ray diffraction pattern comprises peaks at 12.97 and 20.43; or
- (f) said form is a hydrate of celecoxib sodium salt and said X-ray diffraction pattern comprises a peak at 20.13.

44. The pharmaceutical composition of claim 42, wherein the hydrate form is a monohydrate or a trihydrate.

25 45. A pharmaceutical composition comprising a high energy species that drives supersaturation of an API in water, SGF, or SIF.